


IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1015 (LPS)
v.	)	
	)	
SAREPTA THERAPEUTICS, INC.,	)	
	)	
Defendant.	)	REDACTED - PUBLIC VERSION

**SAREPTA’S OPENING BRIEF IN SUPPORT OF ITS MOTION TO STRIKE AND  
DISMISS CLAIMS II-III OF NIPPON SHINYAKU’S FIRST AMENDED COMPLAINT**

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Originally Filed: September 24, 2021  
Redacted Version Filed: October 1, 2021

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## I. NATURE AND STAGE OF PROCEEDINGS

Plaintiff Nippon Shinyaku Co., Ltd. (“NS”) filed its ten-count Original Complaint against Defendant Sarepta Therapeutics, Inc. (“Sarepta”) on July 13, 2021. D.I. 2 (“Original Complaint”). At the same time, NS moved for a preliminary injunction concerning certain *inter partes* review (“IPR”) petitions filed by Sarepta. D.I. 4-5. Briefing on that motion was completed in August, D.I. 5, 18, 25, and the Court today denied the motion for preliminary injunction. D.I. 47. On September 3, 2021, Sarepta timely filed its first Motion to Dismiss Claims II-X of NS’s Complaint and to Strike Paragraphs [REDACTED] of the Complaint. D.I. 32-33 (“First Motion to Dismiss”). In response, NS filed its First Amended Complaint on September 10, 2021. D.I. 39 (“Amended Complaint”).<sup>1</sup>

The Amended Complaint does not raise new claims but adds allegations. In Claim I of the Amended Complaint, NS alleges [REDACTED] [REDACTED] by filing IPR petitions on June 21, 2021.<sup>2</sup> D.I. 39 at ¶¶ 1, 62-76. In Claim II, NS seeks a declaratory judgment (“DJ”) of noninfringement of three University of Western Australia (“UWA”) patents<sup>3</sup> licensed to Sarepta, alleging that its NS’s VILTEPSO<sup>®</sup> product does not infringe. D.I. 39 at ¶¶ 2, 77-89; *see infra* § IV.B. In Claim III, NS seeks a DJ of invalidity with respect to the UWA Patents. D.I. 39 at ¶¶ 2, 90-106; *see infra* § IV.B.1. And in Claims IV-X, NS

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<sup>1</sup> Sarepta’s First Motion to Dismiss NS’s Original Complaint is now moot. For convenience and without waiver of Sarepta’s right to reply to any opposition filed by NS to the present motion, this brief also addresses certain arguments raised in NS’s Opposition to Defendant’s Motion to Dismiss Claims II-X and to Strike Select Paragraphs of Nippon Shinyaku’s Complaint. D.I. 44.

<sup>2</sup> *Sarepta Therapeutics, Inc. v. Nippon Shinyaku Co., Ltd.*, IPR2021-01134; IPR2021-01135; IPR2021-01136; IPR2021-01137; IPR2021-01138; IPR2021-01139; IPR2021-01140.

<sup>3</sup> United States Patent Nos. 9,994,851; 10,227,590; 10,266,827 (collectively, “UWA Patents”).

asserts that Sarepta has infringed seven NS Patents,<sup>4</sup> which are the subject of Sarepta's IPR petitions. *See* D.I. 39 at ¶¶ 3, 107-179. Sarepta respectfully submits this brief in support of its motion under Federal Rules of Civil Procedure 12(b)(1), 12(b)(6), and 12(f) to strike confidential material from the Amended Complaint and dismiss Claims II and III.

## II. SUMMARY OF ARGUMENT

In its Amended Complaint, NS again [REDACTED], failing to articulate an actual case or controversy for this Court to decide. Moreover, Claim II of the Amended Complaint does not satisfy the pleading standard set forth in *Iqbal/Twombly* and the Federal Rules of Civil Procedure, but instead simply denies infringement without factual support. For these reasons, as further described below, Claims II and III of the Amended Complaint should be dismissed.<sup>5</sup>

1. *Claim II should be dismissed under Rule 12(b)(6) for failure to state a claim for declaratory judgment of noninfringement.* *See infra* § IV.B. Like its Original Complaint, NS seeks in its Amended Complaint a declaratory judgment (“DJ”) of noninfringement regarding the UWA Patents. The Amended Complaint's statements regarding noninfringement are threadbare conclusions lacking factual support, mostly repeated from the Original Complaint. D.I. 39 at ¶¶ 2, 89. Such assertions of noninfringement do not rise to the required level of plausibility. *See id.* (discussing *Princeton Digital Image Corp. v. Konami Digital Entm't Inc.*, No. 12-1461-LPS-CJB, 2017 WL 239326, at \*5 (D. Del. Jan. 19, 2017)). In an attempt to evade this issue raised in Sarepta's First Motion to Dismiss, NS now asserts that it does not infringe “because the UWA

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<sup>4</sup> United States Patent Nos. 9,708,361 (Claim IV); 10,385,092 (Claim V); 10,407,461 (Claim VI); 10,487,106 (Claim VII); 10,647,741 (Claim VIII); 10,662,217 (Claim IX); 10,683,322 (Claim X) (collectively, “NS Patents”).

<sup>5</sup> Without conceding to the additional allegations pled in the Amended Complaint, Sarepta does not renew its motion to dismiss Claims IV through X.

Patents are invalid.” D.I. 39 at ¶ 89 (citation omitted). But NS’s assertion of patent *invalidity* fails to plead a viable DJ claim of *noninfringement*, which is a separate issue as a matter of law. *See infra* § IV.B.1 (discussing *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 644-45 (2015)). NS’s attempt to conflate the issues of invalidity and noninfringement cannot suffice, and Claim II should be dismissed for this facial deficiency.

2. *Claims II and III should be dismissed under Rules 12(f) and 12(b)(1) for lack of subject matter jurisdiction and standing. See infra* § IV.C. In its Amended Complaint, NS seeks to establish DJ jurisdiction by [REDACTED] [REDACTED] which should be stricken under Rule 12(f) [REDACTED] [REDACTED]; *see also SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1375 n.1 (Fed. Cir. 2007) (to avoid the risk of a declaratory judgment action, [REDACTED] [REDACTED]). Even if these allegations are not stricken, however, they would not support DJ jurisdiction. Rather, as addressed in detail below, the allegations of the Amended Complaint do not establish a case or controversy sufficient under Article III. *See infra* § IV.C.3. The Court should therefore dismiss Claims II and III.

### III. STATEMENT OF FACTS

Sarepta and NS are both developing and commercializing therapies for the treatment of the same patient population suffering from Duchenne Muscular Dystrophy (“DMD”). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

---

6 [REDACTED]

7 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]—and several weeks before NS filed this action—Sarepta challenged the patentability of the *NS Patents* before the United States Patent and Trademark Office; those IPR petitions remain pending. Sarepta did not, however, allege or pursue infringement of the *UWA Patents* by NS’s VILTEPSO<sup>®</sup> product in any court at that time, and still has not done so. [REDACTED]

[REDACTED]

#### IV. ARGUMENT

##### A. LEGAL STANDARDS

##### 1. Rule 12(b)(6) Standards

A complaint must contain sufficient facts, accepted as true, to state a claim to relief that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56, 570 (2007). Further, a plaintiff’s obligation to provide the grounds of its entitlement to relief “requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555. The Court is not obligated to accept as true “bald assertions,” *Morse v. Lower Merion School District*, 132 F.3d 902, 906 (3d Cir. 1997), or “unsupported conclusions,” *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997).

## 2. Standing and Rule 12(b)(1) Standards for Declaratory Judgment Jurisdiction

Under the Declaratory Judgment Act, a “case of actual controversy” must exist to be justiciable in federal court. *See* 28 U.S.C. § 2201(a); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-27 (2007). An Article III “case or controversy” exists when “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Id.* at 127. In the context of an action for declaratory judgment of patent noninfringement or invalidity, jurisdiction may exist only where there is “an affirmative act by the patentee related to the enforcement of his patent rights.” *Ass’n for Molecular Pathology v. United States Patent & Trademark Office*, 689 F.3d 1303, 1318 (Fed. Cir. 2012), *rev’d in part on other grounds sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013). Plaintiff has the burden to prove an actual controversy exists under the Declaratory Judgment Act. *See Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1329 (Fed. Cir. 2014). The Court has broad discretion whether to proceed with counts arguing for DJ jurisdiction. *See MedImmune*, 549 U.S. at 126-27.

Closely related, a motion to dismiss for lack of standing also may be brought under Rule 12(b)(1), because standing is a jurisdictional matter. *See Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). To satisfy the constitutional minimum for standing, the plaintiff must allege (1) an injury-in-fact (i.e., concrete and actual or imminent, not conjectural or hypothetical); (2) a fairly traceable connection to the defendant’s alleged conduct, and (3) a claim that is redressable. *See Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 102-03 (1998).

### 3. Rule 12(f) Motion to Strike

Rule 12(f) provides that a court “may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). Immaterial matter is “that which has no essential or important relationship to the claim for relief or the defenses being pleaded.” 5 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1382, at 706-07 (1990). Impertinent matter consists of “statements that do not pertain, and are not necessary, to the issues in question.” *Id.* at 711. A Rule 12(f) motion to strike avoids the time and expense of litigating spurious issues by dispensing with those issues before trial. *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir. 1993), *rev’d on other grounds*, 510 U.S. 517 (1994) (citation omitted) (affirming grant of motion to strike where allegations created serious risks of prejudice, delay, and confusion of issues). Grounds for a motion to strike must appear on the face of a pleading or from matters as to which courts may take judicial notice. *Id.* at 1528-29.

#### B. CLAIM II SHOULD BE DISMISSED UNDER RULE 12(B)(6) FOR FAILURE TO STATE A CLAIM OF NONINFRINGEMENT

In determining whether declaratory judgment jurisdiction exists, the Court must look to the elements of the potential cause of action. *See Microsoft Corp. v. SynKloud Techs., LLC*, 484 F. Supp. 3d 171, 181 (D. Del. 2020); *Princeton Digital*, 2017 WL 239326, at \*4-5 & n.12; *cf. Pilot Inc. v. Noco Co.*, No. CV-20-01452-PHX-SRB, 2021 WL 2188525, at \*4 (D. Ariz. Feb. 12, 2021) (“Defendant’s assertion that it needed to only satisfy the jurisdictional requirements of the Declaratory Judgment Act . . . to properly plead noninfringement and invalidity is unsupported”). NS does not satisfy the pleading standard of Rule 8(a) with its conclusory allegations, nor with the matter added by the Amended Complaint:

89. Nippon Shinyaku denies infringing, inducing others to infringe, or contributing to the infringement of any claim of the UWA Patents, either literally or under the doctrine of equivalents. By way of example only and not to limit Nippon Shinyaku’s rights

to assert further non-infringement defenses during the course of the litigation, *Nippon Shinyaku alleges that it does not infringe because the UWA Patents are invalid*. See ¶¶ 90-106, *infra*. A party cannot be liable for infringement of an invalid claim. See, e.g., *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1929 (2015) (“To say that an invalid patents [sic] cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics.”).

D.I. 39 at ¶ 89 (emphasis added). Like its Original Complaint, NS’s Amended Complaint fails to plead any facts whatsoever supporting its noninfringement claim.

### **1. NS’s New Invalidity Allegation Is Insufficient as a Matter of Law to Plead a Claim of Noninfringement**

NS’s Amended Complaint does not cure the deficiencies of its Original Complaint. All that NS adds substantively for Claim II in the Amended Complaint is a misapplication of *Commil* to argue that asserting *invalidity* suffices to plead *noninfringement*. See *id.* This addition fails as a matter of law in pleading noninfringement, however, as *Commil* itself held *the opposite* in strongly distinguishing infringement from invalidity:

[T]he Court explained, “A party seeking a declaratory judgment of invalidity presents a claim independent of the patentee’s charge of infringement.” . . . These explanations are in accord with the long-accepted truth—perhaps the axiom—that infringement and invalidity are separate matters under patent law.

Indeed, the issues of infringement and validity appear in separate parts of the Patent Act. . . . Further, noninfringement and invalidity are listed as two separate defenses, and defendants are free to raise either or both of them. Were this Court to interpret § 271(b) as permitting a defense of belief in invalidity, it would conflate the issues of infringement and validity.

575 U.S. at 643 (citing *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 96-98 (1993)) (other citations omitted).

In this case, NS’s Amended Complaint improperly attempts to “conflate the issues of infringement and validity,” *id.*, and crops a quote from a larger context that, when read in full,

undermines NS's position. *Compare id.*, with D.I. 39 at ¶ 89. At bottom, as held in *Commil*: “Validity and infringement are distinct issues, bearing different burdens, different presumptions, and different evidence.” *Id.* at 644 (citation omitted). To be sure, there can be no infringement liability where a patent is shown to be invalid by clear and convincing evidence. *Id.* But NS misreads *Commil* in suggesting that it can substitute allegations of invalidity for noninfringement here. *See id.* at 643 (“When infringement is the issue, the validity of the patent is not the question to be confronted.”).

District courts have accordingly not accepted patent invalidity as a sufficient basis for pleading noninfringement. In *Princeton Digital*, for example, this Court did not absolve the plaintiff of its deficient *noninfringement* pleading simply because the complaint simultaneously raised *invalidity* claims. 2017 WL 239326, at \*4-5. Instead, the Court required “sufficient facts to make out a plausible claim” of noninfringement by itself, not comingled with invalidity allegations. *Id.* at \*5. Other courts have even determined that a noninfringement allegation claiming only that “an invalid patent cannot be infringed,” *concedes* infringement by waiver:

[Defendants] do not raise a specific ground of non-infringement, and instead rely on broad language of patent invalidity, which is not in compliance with Rule 8 of the Federal Rules of Civil Procedure. . . .  
***Broad claims of non-infringement due to invalidity do not preserve a claim of actual non-infringement under this standard.***

*See Unigene Labs., Inc. v. Apotex, Inc.*, No. 06-CV-5571, 2010 WL 2730471, \*2 (S.D.N.Y. July 7, 2010) (emphasis added), *aff'd* 655 F.3d 1352, 1354 (Fed. Cir. 2011) (affirming determination that Apotex had waived its noninfringement counterclaim). Here, too, NS has not raised “a specific ground of non-infringement,” and instead “rel[ies] on broad language of patent invalidity.” *Id.* Such a speculative prospect of future invalidity is insufficient under the Declaratory Judgment Act and fails as a matter of law to save Claim II.

## 2. NS's Mere Denial of Infringement Also Fails to Sufficiently Plead Noninfringement

The Amended Complaint also fails to meet NS's obligation under Rule 8 "to set forth factual allegations showing *how* each accused product or service specifically does not meet at least one claim limitation." *See Comcast Cable Commc'ns, LLC v. OpenTV, Inc.*, 319 F.R.D. 269, 273 (N.D. Cal. 2017) (dismissing noninfringement claim and holding that the "complaint must go beyond only stating in conclusory terms that each accused product or service meets the elements of non-infringement").

With NS's misapplication of *Commil* negated as a matter of law, its Amended Complaint's remaining statement—i.e., that "*Nippon Shinyaku denies infringing . . . either literally or under the doctrine of equivalents*"—is a mere denial and facially deficient under Rule 8(a). D.I. 39 at ¶ 89 (emphasis added). As the Supreme Court has instructed, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555. Even considering NS's allegation in paragraph 2—i.e., "manufacture, use, sale, offer to sell within the United States, and/or importation into the United States of VILTEPSO<sup>®</sup>, also known as 'viltolarsen' or 'NS-065'"—this simply denies the elements of direct infringement. D.I. 39 at ¶ 2. NS's conclusory allegations are no more than "a formulaic recitation of the elements of a cause of action [and] will not do." *Twombly*, 550 U.S. at 555.

Notably, NS fails to even attempt to identify which of its activities it deems noninfringing vis-à-vis the UWA Patents. *See* D.I. 39 at ¶¶ 2, 89. The Amended Complaint does not point to any facts regarding *how* NS's VILTEPSO<sup>®</sup> product does not meet one or more limitations of any particular claim. As such, NS still fails to identify facts giving rise to an actual controversy of sufficient immediacy for DJ jurisdiction, and effectively seeks an unbounded advisory opinion of noninfringement.

The necessity of applying *Twombly/Iqbal* standards even to DJ claims of noninfringement is illustrated in *Princeton Digital*, which involved similarly sparse noninfringement allegations:

29. Harmonix and EA have not infringed and are not infringing, either directly or indirectly, nor have the[y] contributed to or induced infringement by others, of any valid claim of the '129 patent, either literally or under the doctrine of equivalents.

30. Accordingly, Harmonix and EA are entitled to a declaratory judgment that they have not infringed and do not infringe the '129 patent.

2017 WL 239326, at \*5 (alteration in original). In granting a Rule 12(b)(6) motion to dismiss, this Court held that “Harmonix and EA do not seriously contend that . . . allegations that certain of their products do not meet the limitations of the relevant claims of the patent-in-suit[] are robust enough to meet the *Twombly/Iqbal* standard. And they are not.” *Id.* This was because the paragraphs that made up the counterclaim contained “no facts of any kind, let alone sufficient facts to make out a plausible claim.” *Id.*; accord *Becton, Dickinson & Co. v. NeuMoDx Molecular, Inc.*, C.A. No. 19-1126-LPS, D.I. 56, Tr. at 30:9-24 (D. Del. June 25, 2020) (“I am informed by, among other things, the *Princeton Digital* case that is cited in the briefing . . . I do think that a defendant attempting to assert a counterclaim of noninfringement has to do more than just simply parrot the statute and say ‘I don’t infringe,’ which is essentially all the defendant has done at this point.”).

In sum, the bald assertion that “Nippon Shinyaku denies infringing . . . any claim of the UWA Patents,” without any supporting factual allegations, fails to state a plausible DJ claim of noninfringement. D.I. 39 at ¶ 89. And conclusory claims of patent invalidity cannot save it. *See supra* § IV.B.1. NS’s request for a declaration of no direct or indirect infringement by VILTEPSO® in Claim II of the Amended Complaint should be dismissed under Rule 12(b)(6). *See Princeton Digital*, 2017 WL 239326, at \*5; *Pilot*, 2021 WL 2188525, at \*4 (gathering cases). As such, the Court should dismiss Claim II.



**C. THE COURT SHOULD STRIKE IMPROPER, IMMATERIAL, AND IMPERTINENT STATEMENTS UNDER RULE 12(F) AND INDEPENDENTLY DISMISS CLAIMS II AND III UNDER RULE 12(B)(1) FOR LACK OF SUBJECT MATTER JURISDICTION**

In its Amended Complaint, NS attempts to correct its deficient pleading [REDACTED]

[REDACTED]. NS's efforts fall flat, however, because (1) [REDACTED]

[REDACTED]; and (2) [REDACTED]

[REDACTED] they are insufficient to show a “substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune*, 549 U.S. at 127. Thus, it is proper to dismiss Claims II and II on this independent basis for lack of subject matter jurisdiction under Rule 12(b)(1), as further described below.

**1. NS's Allegations [REDACTED] Should Be Stricken**

NS seeks to establish DJ jurisdiction based [REDACTED]

[REDACTED]:

There is an actual case and controversy between Nippon Shinyaku and Sarepta regarding the UWA Patents, as evidenced [REDACTED]

[REDACTED] This actual case and controversy is also evidenced [REDACTED]

D.I. 39 at ¶ 78 (Claim II) (emphases added); *id* at ¶ 91 (Claim III); *see also id.* at ¶¶ 2, 11.

As detailed below, [REDACTED]

\_\_\_\_\_ should be stricken under Rule 12(f) as “impertinent” and “immaterial.” *See* Fed. R. Civ. P. 12(f). To the extent NS’s allegations above \_\_\_\_\_

then such allegations should also be stricken. *See infra* § IV.C.2.

On its face, the Amended Complaint

. NS does not deny this. *See* D.I. 44 at 5; *see also id.* at 1-2, 5-6.

\_\_\_\_\_ in an attempt to establish DJ jurisdiction for Claims II (noninfringement) and III (invalidity), \_\_\_\_\_

In *SanDisk*, the Federal Circuit stated that “[t]o avoid the risk of a declaratory judgment action,” [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[illegible][illegible]

\_\_\_\_\_ they  
still do not supply a jurisdictional basis for NS's DJ claims because they do not include allegations  
showing a substantial controversy of sufficient immediacy. *See infra* § C.3.

**2. NS's Description of Alleged [REDACTED]  
[REDACTED] Should Also Be Stricken**

In an effort to buttress its deficient jurisdictional allegations, NS now offers new allegations in its Amended Complaint [REDACTED]

[REDACTED] As with the four paragraphs of the Original Complaint that were resurrected in the Amended Complaint, *see supra* § C.1., these additions should also be stricken [REDACTED]. But even if considered, they provide no basis for DJ jurisdiction against the UWA Patents due to NS's failure to plead facts showing a substantial controversy of sufficient immediacy.

First, [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The Court should therefore strike [REDACTED]

[REDACTED] If the Court strikes these paragraphs pursuant to Rule 12(f), the core of NS's jurisdictional argument would be hollowed-out and dismissal for lack of DJ subject matter jurisdiction should follow as a matter of law under Rule 12(b)(1) or Rule 12(b)(6).<sup>9</sup> See *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) ("The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the patentee."); cf. *id.* (as a standing matter, "[a]bsent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy.").

If the Court declines to strike the paragraphs, it should still dismiss Claims II and III for lack of subject matter jurisdiction because none of the cited allegations show sufficient immediacy of legal action.

### **3. NS's Allegations Are Insufficient to Establish Declaratory Judgment Jurisdiction**

Even if the Court does not strike any of the matter raised above, NS still does not sufficiently plead a "substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 127; *Prasco*, 537 F.3d at 1335-36.

NS's remaining allegations regarding the UWA Patents, D.I. 39 at ¶¶ 13, 14, including NS's allegation that the claims of the UWA Patents were "aimed at capturing VILTEPSO<sup>®</sup>," *id.* at ¶ 14, also provide no basis for DJ jurisdiction regarding these patents. NS offers no basis for the supposed imminent infringement suit by Sarepta on the UWA Patents. Instead, NS's Amended

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<sup>9</sup> Coupling Rules 12(f) and other 12(b) grounds for this purpose is permitted. See *Rutter Grp. Practice Guide Fed. Civil Procedure Before Trial (Nat'l Ed.)*, at [9:372-9:372:1] (2021) (a pre-answer motion to strike joined with a motion to dismiss for failure to state a claim may eliminate one or more of claims).

Complaint acknowledges that the UWA Patents cover Sarepta's VYONDYS<sup>®</sup> 53 product and are listed in the FDA Orange Book because they protect Sarepta's VYONDYS<sup>®</sup> 53 product. *Id.* at ¶ 14. These patents were all filed after all claims of related U.S. Patent No. 8,455,636 were canceled in an interference proceeding,<sup>10</sup> *Univ. of W. Australia v. Academisch Ziekenhuis Leiden*, Interference No. 106,007, Paper No. 474 (Apr. 29, 2016), and the Federal Circuit appeal of that decision was withdrawn. *Academisch Ziekenhuis Leiden v. Univ. of W. Australia*, No. 2016-2262 (Fed. Cir. July 26, 2017) (Stipulation of Voluntary Dismissal). Thus, the UWA Patents could have been filed to further protect Sarepta's VYONDYS<sup>®</sup> 53 product after the interference decision became final.

Finally, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>10</sup> The judgment from the Patent Trial and Appeal Board ordering all claims of U.S. Patent No. 8,455,636 to be canceled issued in April 2016 and was followed by the filing of U.S. Patent No. 9,994,851 (filed Sept. 14, 2017) and U.S. Patent Nos. 10,227,590 and 10,266,827 (both filed Aug. 24, 2018).



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

To determine “whether a justiciable controversy is present, the analysis must be calibrated to the particular facts of each case.” *Matthews Int’l Corp. v. Biosafe Eng’g, LLC*, 695 F.3d 1322, 1328 (Fed. Cir. 2012). Here, [REDACTED], Sarepta took action only to challenge the *NS Patents* before the PTAB, not to pursue infringement by VILTEPSO® of the *UWA Patents*. See D.I. 39 at ¶¶ 19, 86, 99. In view of NS’s allegations in the Amended Complaint

[REDACTED]

[REDACTED], in addition to the insufficiency of NS’s amended pleading, the Court should determine that NS has failed to adequately plead DJ jurisdiction for Claims II and III and dismiss them.

## V. CONCLUSION

For the foregoing reasons, the Court should grant Sarepta’s Rule 12 motion, strike ¶¶ [REDACTED] of the Amended Complaint, and dismiss Claims II and III.

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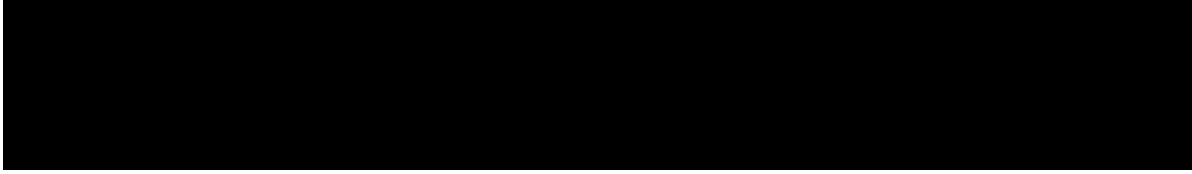
September 24, 2021

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# EXHIBIT A





[REDACTED]

~~~~

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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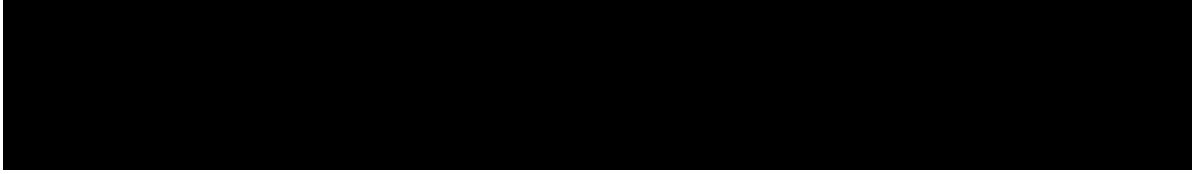
[REDACTED]  
[REDACTED]

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[REDACTED]



# EXHIBIT B



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**CERTIFICATE OF SERVICE**

I hereby certify that on October 1, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on October 1, 2021, upon the following in the manner indicated:

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